THERAPEUTIC GOODS ADMINISTRATION

Consultation: The scheduling policy framework and advertising of pharmacist-only medicines (Schedule 3 substances)

Date
May 2017
INTRODUCTION AND GENERAL COMMENTS

The Pharmacy Guild of Australia (the Guild) welcomes the opportunity to provide further comment on the scheduling policy framework and advertising of Pharmacist Only Medicines (Schedules 3 substances).

The Guild supports the ‘National Strategy for Quality Use of Medicines’ (QUM) and believes that QUM is best supported by the supply of medicines through a pharmacy where there is access to professional support and advice from a pharmacist, with assistance provided from trained pharmacy assistants, within a quality-assured framework.

The Guild also believes the current scheduling classification system for medicines with two non-prescription categories (Schedule 2 and Schedule 3) and two prescription categories (Schedule 4 and Schedule 8) effectively balances convenience and accessibility with public safety. In addition, separate non-prescription categories (Schedule 2 and Schedule 3) facilitates consumer access to safe and effective medicines supported by professional advice according to the level of risk associated with the medicine.

The Guild has focussed its responses mainly on issues of direct relevance to community pharmacy, providing comments on the specific questions where applicable.

GOVERNANCE

Policy Recommendation 1 – Split the Scheduling Policy Framework (SPF) into a policy document and a guidance handbook

The Guild has no objections to this recommendation.

Policy Recommendation 2 – Establish an informal working group (comprising state and territory representatives, healthcare professionals and consumers) to provide advice on possible amendments to the SUSMP

The Guild believes there is merit in this recommendation and believes representation of community pharmacy in such a working group is essential.

Details on how such a working group would operate should be outlined for further consideration.

DECISION-MAKING PRINCIPLES

Ongoing Improvements 1 – Applicants presenting to the advisory committees

The Guild has no objection in conducting a pilot exercise to allow applicants to formally present to the advisory committees. If this approach was adopted on a permanent basis, then other relevant stakeholders (not just applicants) should be eligible to make an in-person representation.
Business Improvement Measures 1 – Structure and content of the committee’s advice

a. A clearer explanation of the cascading principle and how it is applied should be included in the SPF

b. The structure and the content of the Committee’s advice, and the delegate’s reasons should be revised to ensure they are meeting the needs of stakeholders

The Guild is supportive of both these measures as they will add clarity and transparency to the scheduling decision making process.

TRANSPARENCY

Business Improvement Measures 2 – Public summary of the scheduling submission and other communication processes

a. A summary for public dissemination should be provided by scheduling applicants, and this would be published as part of the public consultation process. This could be included in the application template. If an appropriate summary is not provided by the applicant, the default option could be that the entire (de-identified) application would be published for public consultation.

The Guild supports improved transparency regarding information on the decision making process. The Guild believes all information relevant to a scheduling application should be made publicly available.

The Guild would also support publishing the names of organisations that provide pre-meeting submissions to scheduling proposals.

b. A mechanism should be developed to alert stakeholders of items being considered for scheduling. For example, the delegate could identify a small number of affected stakeholders for comment, and the Secretariat could contact them directly.

The Guild would support this mechanism. Providing earlier notice regarding scheduling proposals would enable stakeholders to better prepare internal work flow and resources.

RISK-BENEFIT VALUE TREE

Business Improvement Measures 3 – Greater emphasis on benefits as well as risks

The Guild is open to the adoption of a formal methodology for assessment of risks and benefits. A value tree is of most relevance when considering scheduling amendments between Schedule 4 (Prescription Only Medicine) and Schedule 3 (Pharmacist Only Medicine).

In relation to Schedule 2 and Schedule 3 amendments, the Guild contends that once a product is available over-the-counter (OTC), the benefits to consumers of further down scheduling are limited. Continually down-scheduling medicines that are already available OTC (particularly scheduling exemptions) heightens the risk of medicine misadventure and/or delayed or missed diagnosis of conditions with little to no additional benefit to consumers.
Therefore, a value tree framework could be included as an optional tool for specific applications particularly in relation to Schedule 4 down-scheduling proposals.

**INTERIM DECISIONS**

**Policy Recommendation 3: Public consultation on interim decisions**
The Guild has no objection to removing the restrictions around who can provide responses to interim scheduling decisions and allowing full public consultation and comment.

**Business Improvement Measure 4: Guidance on legal nature of scheduling and scheduling decisions**
The Guild has no objection to the inclusion in the SPF of an explanatory statement of the legislative nature of scheduling decisions.

**TIMING OF SCHEDULING DECISIONS**

**Business Improvement Measure 5: Decision transparency and information sharing**
The Guild supports including an explanation in the SPF of jurisdictional requirements for decisions to enhance stakeholder understanding.

The Guild also supports measures that alert stakeholders such as community pharmacy to scheduling changes, allowing them more time to prepare and adjust to the change. Pharmacy organisations such as the Guild require adequate time to inform and prepare pharmacy staff in regards to scheduling changes. This applies to most scheduling changes due to the regulatory implications for community pharmacies, such as the level of pharmacist involvement in determining therapeutic need for the medicine as well as the storage requirements for the medicine.

**PROACTIVE CONSIDERATION OF CANDIDATE SUBSTANCES FOR RESCHEDULING**

**Ongoing Improvements 3 – Proactive identification of substances for rescheduling**
The Guild has no objection to implementing a system for proactively identifying substances for rescheduling. Community pharmacy input and representation in this process is essential given the implications for pharmacies associated with most, if not all scheduling changes.
TOOLS FOR BETTER MANAGEMENT OF RESCHEDULED MEDICINAL SUBSTANCES

Policy Recommendation 5: New Controls for certain medicines that have been down-scheduled to pharmacist only classification (S3) – New Appendix in the Poisons Standard

Additional Controls for Schedule 3 medicines

The Guild supports the principle and intent of this recommendation. The Guild in previous submissions on scheduling policy has indicated that there would be merit in exploring ways to make the Poisons Standard more flexible to allow greater patient access while ensuring medicines are supplied safely and appropriately.

As noted in the discussion paper, other comparable countries (e.g. New Zealand) have enabled several prescription only medicines to be supplied over-the-counter by a pharmacist, subject to a series of controls that are additional to the standard supply regulations for Pharmacist Only medicines and are specific to the medicine. These controls include:

- Additional patient criteria that apply when the medicine is supplied over-the-counter. Such as
  - patients must be within a certain age range
  - patients has been previously diagnosed with the condition the medicine is intended to treat.
- Limits on dosage strength and/or pack size
- A screening tool/questionnaire
- Mandatory training for pharmacists
- A requirement to inform the individual patient’s doctor regarding supply (subject to the consent of the patient)

The Guild emphasises that not all of these controls are applicable to all medicines in this context. The appropriate controls should be considered on a molecule specific basis.

If a new appendix were to be developed, the title would need to be broad with the specific controls relating to each medicine outlined in individual listings under the appendix. As a suggestion, the appendix could be titled: ADDITIONAL CONTROLS ON SUPPLY OF POISONS INCLUDED IN SCHEDULE 3. This would reflect the wording of current appendices in the Poisons Standard.

From a practical perspective, if such an appendix were to be created, an applicant would apply to create or amend a Schedule 3 entry for a molecule and propose listing on this new appendix, outlining the specific set of conditions for supply. These scheduling applications would then be considered through the current scheduling decision making process. States and Territories would need to make a one-off amendment to their respective Poisons Regulations to recognise this new appendix in order to ensure these scheduling changes can be automatically applied in each jurisdiction.

The Guild believes the listing of medicines in this new appendix should be carefully considered on a case-by-case basis.

Mandatory recording of medicines

Currently, the Poisons Standard does not stipulate requirements for mandatory recording of medicines. Thus the mandating of recording medicines must occur via changes to each individual
State/Territory poisons legislation. This invariably causes delay and inconsistency between jurisdictions. For example, the recording of pseudoephedrine supply is mandated in each State and Territory (except Victoria and Tasmania) and there are currently variations between jurisdictions regarding this requirement. This reduces the effectiveness of the recording system. The Guild believes there is an opportunity to incorporate the mandatory recording of medicines into Poisons Standard by creating a new appendix that lists medicines that are subject to mandatory recording. This would ensure national consistency.

**Prescription ‘except when’ model**

The Guild would also like to propose that a new schedule as part of the Poisons Standard be developed that specifies additional controls or requirements for certain prescription medicines to enable pharmacists who meet certain criteria to supply these medicines without the need for a patient to present a prescription.

This system operates in New Zealand for some medicines and is already works in some form in Australia for influenza vaccines in all States and Territories. The influenza vaccine (and in some states the pertussis and measles vaccines) is able to be administered without a prescription by a pharmacist who has completed the necessary training. This mechanism could be included for a wider range of Schedule 4 medicines by inclusion in an appendix to the SUSMP.

Examples from overseas jurisdictions include:

**New Zealand:**

- Sildenafil is a prescription medicine, except in medicines for oral use containing 100 milligrams or less per dose unit when sold in the manufacturer's original pack containing not more than 12 solid dosage units for the treatment of erectile dysfunction in males aged 35-70 years by a registered pharmacist who has successfully completed a training program endorsed by the Pharmaceutical Society of New Zealand.
- Calcipotriol is a prescription medicine, except in medicines containing not more than 50 micrograms per gram or per milliliter and when sold in a pack of not more than 30 grams or 30 milliliters by a pharmacist to an adult with mild to moderate psoriasis previously diagnosed by a doctor.
- Trimethoprim is a prescription medicine, except in medicines for oral use containing 300 milligrams or less per dose unit when sold in a pack of 3 solid dosage units to a woman aged 16-65 years for the treatment of an uncomplicated urinary tract infection by a registered pharmacist who has successfully completed the New Zealand College of Pharmacists' training in the treatment of urinary tract infections.

**United Kingdom**

- Azithromycin for chlamydia is Prescription Only unless certain conditions are met. The product can only be distributed to pharmacies which are registered to provide a chlamydia test which is performed in an accredited laboratory and a system to confirm laboratory results are managed to ensure records are kept secure at all times. In addition a suitably accredited pharmacy training package should be supplied to cover all aspects of supply.
- Trimethoprim, Finasteride and Northisterone are available under *Patient Group Directions* (documents permitting the supply of prescription-only medicines to groups of patients without individual prescriptions) under the National Health Service.
The Guild recommends that serious consideration be given to an appendix for Schedule 4 medicines to enable the supply of particular medicines under specific supply protocols by a pharmacist.

Allowing access to Prescription 'except when' benefits patients and this has been proven by the increased rates of influenza vaccination rates in Australia since pharmacists have been allowed to vaccinate.1 Allowing certain Prescription Only medicines to be available from a pharmacist under certain conditions will improve access to medicines for consumers who cannot access a GP with a non-emergency condition in a timely manner.

The appendix could be called EXEMPTIONS FOR CERTAIN SUPPLIES OF POISONS INCLUDED IN SCHEDULE 4 and the details of the exceptions would depend on the particular medicine.

**IMPROVING THE CLARITY OF THE SPF**

**Business Improvement Measures 6: Improving the clarity of SPF**

The Guild considers ‘second or all-in-class’ rescheduling proposals should only be considered if the risk profile, route of administration, strength and pack size are similar. This should be determined on a case-by-case basis.

**ADVERTISING OF SCHEDULE 3 (PHARMACIST ONLY) MEDICINES**

As stated in previous submissions on this topic, the Guild supports reforms to the Pharmacist Only Medicine advertising regulations, so as to enable these products to be advertised under the following conditions:

- Sufficient time is allocated for pharmacists to become familiar with the increased availability, demand and associated professional responsibilities when products are rescheduled from Schedule 4 to Schedule 3.
- Industry assists the profession through both consultation and funding to develop relevant professional support materials for the supply of Schedule 3 medicines.
- Pharmacists are provided with relevant training to support the professional supply of Schedule 3 medicines.
- All advertisements inform consumers that Schedule 3 products are only available in consultation with a pharmacist.
- All advertisements include a direction to ‘Ask Your Pharmacist’.
- The last two requirements are incorporated into appropriate legislation/ regulation (Therapeutic Goods Act, Advertising Code).
- Adequate enforcement and sanctions are applied in circumstances where an advertisement is found not to have complied with the relevant regulations.

In essence, the Guild sees the promotion of Schedule 3 medicines to consumers not as ‘advertising’ in the sense that is applicable to other items of commerce, but rather communicating to consumers the availability of medicines suitable for their health condition without the need for a prescription, subject to the mandatory assessment and confirmation by a pharmacist.

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The Guild acknowledges that some Schedule 3 medicines are not suitable to be communicated directly to the public and hence an advertising restriction in some form remains appropriate.

The Guild also acknowledges some concerns that Schedule 3 advertising may lead to consumers purchasing unnecessary or potentially unsafe medicines due to low health literacy. However, there is a benefit for consumers in being informed about medicines via regulated and responsible communication messages that emphasise a pharmacist will ultimately determine whether a particular medicine is suitable.

Irrespective of whether Appendix H remains a list of medicines permitted to be advertised or is modified to become a list of medicines prohibited from advertising, the Guild considers it essential that a policy mechanism remains available to restrict advertising of Schedule 3 medicines where it is clearly not in the public interest for a medicine to be advertised.

The current Schedule 3 guidelines for brand advertising places a significant burden of proof on an applicant to demonstrate that allowing advertising of a Schedule 3 medicine is in the public interest. This is despite the fact that key factors for Schedule 3 medicines (outlined in the Schedule Policy Framework) include:

- **Point 1.** The medicine is substantially safe with pharmacist intervention to ensure the quality use of the medicine. There may be potential for harm if used inappropriately.

- **Point 3.** The risk profile of the medicine is well defined and the risk factors for adverse events and interactions are known, identifiable and manageable by a pharmacist. ²

Given these are two elements of what defines a Schedule 3 medicine, it is reasonable that advertising of Schedule 3 medicines should be permitted (subject to the conditions outlined above) unless it is clearly not in the public interest to do so.

Consideration on whether a Schedule 3 medicine should be allowed for advertising should continue to be considered through the current scheduling decision making process when a medicine is down scheduled from Schedule 4 to Schedule 3.

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² Scheduling Policy Framework, Factors for Schedule 3 (Pharmacist Only) Medicines